REMARKS

The Specification has been amended to replace the Title with that suggested by the Examiner, "Powderous Lupin Protein Formulations with Fat-Soluble Active Agent". Support is found in the Specification at, for example, page 1, lines 7-9; and from the original Title.

The Specification has been amended on page 3 to correct a grammatical phrase in the manner suggested by the Examiner.

Claim 1 has been amended to recite "in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked." Support for the amendments is found in the Specification at, for example, Page 1, lines 7-9 and 16-17; and Page 2, line 19 to Page 3, line 10; and in original claims 1, 8 and 9 of the International application. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973); and MPEP §§ 608.01(o) and (l).

Claim 5 has been amended to replace "comprising mixtures of native lupin protein compositions as defined in claims 2-4" with the recitation "wherein the native lupin protein composition is selected from the group consisting of a lupin protein isolate having a protein content of more than 90 wt.-%, a lupin protein concentrate having a protein content of about 60-90 wt.-%, a lupin protein flour having a protein content of about 40-60 wt.-%, and mixtures of any of the foregoing." Support for the amendments is found in the Specification at, for example, Page 1, line 16 to Page 2, line 4; and original claims 1-5. (Id.)

Claims 7, 8 and 12 have been amended as shown above.

Claim 9 has been amended to delete the multiple dependency, such that dependency is to claim 1. Support for the amendment is found in the Specification at, for example, Page 3, lines 16-18; and original claim 10.

Claim 13 has been amended to delete language starting with "and if appropriate," to the end of the claim. Support for the amendment is found in the Specification at, for example, page 2, lines 19-25; Examples 1 and 3; and original claim 11. (Id.)

Claim 14 has been added. Support for the claim is found in the Specification at, for example, Page 2, lines 7-8; Page 4, lines 1-2; and original claim 7. (Id.)

Claim 15 has been added. Support for the claim is found in the Specification at, for example, Page 2, lines 19-20; and original claim 8. (Id.)

Claim 16 has been added. Support for the claim is found in the Specification at, for example, Page 2, lines 24-25; and original claim 13.

Claim 17 has been added. Support for the claim is found in the Specification at, for example, Page 2, lines 27-32; and original claim 11.

It is respectfully submitted that no new matter has been added by any of the amendments.

Objections

The Examiner objected to the Specification. (Paper No. 20081014 at 2.) In making the objection, the Examiner asserted that the Specification "contains the incomprehensible phrase, 'The spray-drying can effected be using conventional

technology of spray-drying ...' (pg. 3, lines 6 & 7). Examiner suggests [sic] the phrases should read, 'The spray-drying can be accomplished by using conventional spray-drying technology...'." (Id.)

With a view toward furthering prosecution, the Specification has been amended as requested by the Examiner.

The Examiner also asserted that "[t]he title of the claimed invention is not descriptive. A new title that more clearly indicates the claimed invention is required. The Examiner suggests the title 'Powderous Lupin Protein Formulations with Fat-Soluble Active Agent'." (Id. at 3.)

With a view toward furthering prosecution, the Title has been amended as suggested by the Examiner.

Claims 5 and 9 were objected to under 37 CFR § 1.75(c) as being in improper multiple dependent form. (Id.) In making the objection, the Examiner asserted that "[c]laim 5 is improper because a multiply dependent claim can only refer back in the alternative [and claim] 9 is improper because a multiply dependent claim cannot depend from another multiply dependent claim (i.e. claim 5)." (Id.)

With a view toward furthering prosecution, claims 5 and 9 have been amended to address the Examiner's concerns.

In view of the foregoing, it is submitted that all of the bases for objection have been rendered moot. Reconsideration and withdrawal of the objections are requested.

Indefiniteness Rejection

Claims 1-9, 12 and 13 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. (Id.)

Regarding claim 1, the Examiner asserted that the phrases "--matrix of native lupin protein-- and ... --the protein is cross-linked-- ... are seemingly mutually exclusive because, insomuch as the invention recites cross-liked [sic], the Examiner believes the native protein to exist as a non-cross-linked protein and upon cross-linking the protein is no longer to be considered a native lupin protein. The claim is internally inconsistent for the aforementioned reason. " (Id.)

To forward prosecution in the present application, claim 1 has been amended to recite "[s]table powderous formulations comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked."

The legal standard for definiteness is whether a claim reasonably apprises those of skill in the art of its scope. *In re Warmerdam*, 31 USPQ 2d 1754, 1759 (Fed. Cir. 1994). It is submitted that one skilled in the art would understand that amended claim 1, which recites that the matrix is "formed from" a native lupin protein composition and that the protein "in the matrix" is cross-linked is internally consistent. Accordingly, we respectfully submit that claim 1 is sufficiently definite under 35 USC § 112, second paragraph.

Regarding claim 5, the Examiner asserted that "it is unclear what [sic] meant by --mixtures of native lupin protein compositions-- as any native lupin protein

composition would necessarily be a mixture of native lupin proteins." (Paper No. 20081014 at 4.)

To forward prosecution in the present application, claim 5 has been amended to recite "wherein the native lupin protein composition is selected from the group consisting of a lupin protein isolate having a protein content of more than 90 wt.-%, a lupin protein concentrate having a protein content of about 60-90 wt.-%, a lupin protein flour having a protein content of about 40-60 wt.-%, and mixtures of any of the foregoing."

"In rejecting a claim under the second paragraph of section 112, *it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to* ascertain the scope of protection defined by the claim when read in light of the supporting specification." *Ex parte Cordova*, 10 USPQ2d 1949, 1952 (Board of Pat. App. and Int. 1989), citing *In re Moore*, 169 USPQ 236 (CCPA 1971). The Specification on page 1, lines 16 to Page 2, line 4, recites that such lupin protein concentrates, isolates, and flours having the recited protein contents are "[e]xamples of such native lupin protein compositions." (Page 1, lines 17-18.) Accordingly, it is submitted that one skilled in the art would understand what is recited in amended claim 5.

Regarding claims 7, 8 and 12, the Examiner asserted that "the phrase 'particularly' renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention." (Paper No. 20081014 at 4.)

With a view toward furthering prosecution, claims 7, 8, and 12 have been amended to address the Examiner's concerns.

Regarding claim 13, the Examiner asserted that "[i]t is a matter of subjective interpretation what exactly the term 'and if appropriate' means. The specification gives no guidance as to what would render the step appropriate. Claim 13 is rejected because it cannot be determined what exactly is meant by -if appropriate--. Furthermore, it is unclear if Applicants intend this to be an optional step." (Id.)

To forward prosecution in the present application, claim 13 has been amended to delete "and if appropriate, submitting the dry powder to cross linking the protein by heat treatment or by treatment with a cross linking enzyme." The Specification discloses that the heat treatment and enzyme treatment are optional. (See page 2, lines 23-25; Examples 1 and 3.) Claim 13 has been amended (and dependent claim 17 has been added) to address the Examiner's concerns.

In view of the foregoing, it is submitted that each of the indefiniteness rejections has been rendered moot. Reconsideration and withdrawal of the rejections are requested.

Obviousness Rejection

Claims 1-4, 6-8, and 10-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fitchett et al., WO 1999/11143 ("Fitchett"), in view of Perrier et al., U.S. Patent No. 5,912,016 ("Perrier") and Altemueller et al., U.S. Patent No. 6,423,364 ("Altemueller"), "as evidenced by" Gerrard (Trends in Food Science and Technology, 13, 2002, pgs. 391-399) and Rahman (Handbook of Food Preservation, Marcel Dekker, 1999).

Fitchett is directed to "lupin protein compositions, and particularly to lupin protein concentrates and isolates. (Abstract, line 1.) "In particular," Fitchett is directed to "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions." (Abstract, line 2.) Fitchett also discloses processes for preparing emulsions and gels. (See, e.g., Summary of the Invention, page 2, lines 34 to page 5, line 32.) In addition, Fitchett discloses "various functional food ingredients comprising the emulsion or gel of the invention." (Page 4, lines 19-20.)

Perrier discloses particles, which are "microparticles or nanoparticles, of crosslinked plant proteins, ... the process for their preparation and ... cosmetic, pharmaceutical or food compositions in which they are present." (Column 1, lines 5-9) (emphasis added.) Perrier also discloses that "[t]hese particles comprise, at least on the surface, a wall formed of plant proteins crosslinked ... by means of interfacial crosslinking between the plant proteins and an acylating polyfunctional crosslinking agent comprising at least two actylating groups, covalent bonds being formed between the acylatable groups of the proteins and the acyl groups of the acylating polyfunctional crosslinking agent." (Abstract, lines 1-8.) Perrier further discloses that the produced particles are "especially spheres or capsules such as nanospheres or nanocapsules and microspheres or microcapsules, which ... encapsulate substances, particularly active principles...". (Col. 8, lines 35-39) (emphasis added.)

Altemueller discloses a "functional food ingredient [that] contains an unrefined plant protein material. The unrefined plant protein material ... is obtained by hydrating a particulate or flaked unrefined plant protein material ..., partially denaturing at least a portion of plant protein contained in the hydrated unrefined plant protein

material, and drying the hydrated partially-denatured unrefined plant protein material." (Abstract, lines 1-10.) The plant protein material may be, according to Altemueller, various indicated materials including "lupin containing materials". (Col. 6, lines 3-7.) Altemueller discloses, however, that unrefined soy protein material is preferred. (Col. 5, lines 60-63; and all Examples.) Altemueller further discloses that "at least a portion of the soy protein in the unrefined soy protein material is irreversibly partially denatured by exposure to elevated temperatures...". (Col. 25, lines 49-51.)

Rahman is a generic document which discloses "Drying and Food Preservation". (Chapter title.) Rahman discloses that "[d]rying is a method of water removal to form final products as solids...". (Page 173, paragraph 2, line 1.)

Gerrard discloses "[p]rotein-protein crosslinking in food: methods, consequences, [and] applications." (Title.) Various types of crosslinking are disclosed. (Pages 391-394, including Figs. 1 and 2.)

The Examiner asserted that he "has interpreted recitation [sic] of claim 1, --cross-linked lupin protein--, to comprise any cross-linking that would result from heating (claim 11) or treatment with a cross-linking enzyme (claim 12)." (Id.) We submit that it is improper for the Examiner to "read in" any limitation into a claim that is not present in the claim as written.

In making the rejection, the Examiner asserted:

> Fitchett et al. teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are [sic] widely used in the food industry (pg. 1, lines 9-15). Fitchett et al. further teaches, "Lupins have long been recognized as a viable alternative to soya as a source of vegetable protein for human consumption" (pg. 2, line 7). Fitchett et al. further

> teaches, "It has long been known that the protein content of lupin seeds is equal to that of whole soya beans, and it has been exploited for years as a sources [sic] of (non-functional) protein in animal feeds" (pg. 2, lines 12-14). Fitchett et al. further teaches "lupin concentrates and isolates per se are known ...and these isolates/concentrates are also known to affect the chemical/physical behavior of foodstuffs in which they are incorporated" (pg. 2, lines 15-17).
>
> Fitchett et al. teaches an emulsion comprising lupin protein composition, water and fat (pg. 2, line 35), where the emulsion may contain any suitable ratio of protein composition, water and fat (pg. 3, line 1). Fitchett notes that by "fat" is meant fats which are liquid at room temperature and, "often referred to as oils" (pg. 2, line 38 & pg. 3, line 1). Fitchett further teaches the example wherein palm fat is used (pg. 3, line 28). Fitchett et al. further teaches, the lupin protein is preferably present in substantially native form which is associated with higher functionality (pg. 4, lines 10-12). Fitchett et al. further teaches the examples of products covered by the invention including a fat-filled powder (pg. 4, lines 32-33). Fitchett et al. further teaches, "It may be desirable to derivatize or physically modify the lupin protein, for example...denaturing the proteins ... by heating ...or by partial. ..enzymatic digestion" (pg. 6, lines 8-10).

(Id. at 5-6.)

The Examiner acknowledged, however, that Fitchett "does not expressly teach cross-linking the lupin protein nor a specific fat-soluble active ingredient...". (Id. at 7.)

To fill these acknowledged gaps, the Examiner asserted that "[t]he deficiency in cross-linking the lupin protein and a fat-soluble ingredient is cured by Perrier et al.; and the deficiency in powdered formulation is cured by Altemueller et al. Rahman provides motivation for producing a powder formulation and Gerrard teaches

the chemistry of protein-protein crosslinking including Maillard and transglutaminase initiated cross-linking." (Id.)

Regarding Perrier, Antemueller, Rahman, and Gerrard, the Examiner asserted:

> Perrier et al. teaches particles of cross-linked plant proteins (title) wherein the particles "...encapsulate substances, particularly active principles, including lipophilic active principles such as vegetable, mineral or synthetic oil, vitamin A and vitamin E derivatives ... " (col. 8, lines 38-41). Perrier et al. further teaches it is well known in the art that encapsulation of active ingredients has the advantages of protecting the ingredients as well as controlling the release rate at the site of use (col. 1, lines 12-15). Perrier et al. further teaches the example in which microcapsules with a wall formed of crosslinked lupin proteins is made by dissolving sweet white lupin flour in water containing a succinate buffer of pH=6, the mixture is heated, the supernatant is separated, glucose is added [and] emulsification and crosslinking are then carried out (example 9).
>
> Altemueller et al. teaches a novel functional food ingredient comprising an unrefined plant protein material wherein the functional food ingredient is hydrated, partially denatured and dried (abstract). Altemueller et al. further teaches, "The plant protein material may be any unrefined protein material derived from a plant... Representative...examples of such plant protein materials include...lupin protein containing materials..." (col. 5 line 67, col. 6 lines 1 & 3-5). Altemueller et al. further teaches drying of the processed plant protein material, "The flash vaporized unrefined soy protein material slurry may be spray-dried to produce the dry unrefined soy protein material food ingredient of the present invention" (col. 26, lines 33-35).
>
> Rahman gives several motivations for producing a powder formulation including, "... to increase shelf life, reduce packaging and storage costs, lower shipping weights, improve sensory attributes, encapsulate flavors, and preserve nutritional value in some cases" (pg. 173, paragraph 3).

> Gerrard teaches protein-protein crosslinking in food (title) which comprises formation of covalent bonds between polypeptide chains within a protein or between proteins (pg. 391, col. 2, lines 24-27). Gerrard further teaches, "Food processing often involves high temperatures, extremes in pH, particularly alkaline, and exposure to oxidizing conditions and uncontrolled enzyme chemistry. Such conditions result in the introduction of protein crosslinks, producing substantial changes in the structure of proteins, and therefore the functional and nutritional properties of the final product." (pg. 391, col. 2, lines 38-45). Gerrard further teaches different types of crosslinking including, disulfide crosslinks (pg. 392)[,] crosslinks derived from the Maillard reaction (heat initiated) and crosslinks formed via the enzyme transglutaminase (also see Figures 1 & 2).
>
> (Id. at 7-8.)

The Examiner concluded that it would have been obvious "to combine the teachings of Fitchett et al. with the teachings of Perrier et al. and Altemueller et al. because they each teach plant protein compositions for use in food products. The processing of foods, which is common place in modern society, provides for an increased shelf life, consistent and appealing texture, and enhanced flavor. Cross-linking of proteins provides a means for controlling the functional properties of foods, such as the texture. A cross-linked protein can also provide a matrix for additional beneficial ingredients such as fat-soluble vitamins. A dry powdered product would be very desirable for functional proteins for use as food additives because the storage conditions would be more favorable and the shipping costs would be reduced. It would have been prima facie obvious at the time of the claimed invention that a cross-linked protein would provide for an enhanced food additive. It would have been prima facie obvious that vitamin enrichment would provide for a more nutritious and therefore

desirable product. It would have been prima facie obvious at the time of the claimed invention to produce a powder formulation from the emulsion taught by Perrier et al. [because, as] suggested by Rahman, the shelf life would increase and the shipping costs would decrease[,] adding value to the product. Furthermore, it is prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a plant protein powder." (Id. at 9.)

The Examiner further asserted that "[f]rom the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success, for example the prior art teaches cross-linking of different proteins using various methods, as discussed above. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary." (Id. at 10.)

To forward prosecution in the present application, claims 1, 7, 8, 12, and 13 have been amended. In particular, claim 1, as amended, recites "[s]table powderous formulations comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked."

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the cited documents by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test "***must be based on objective evidence <u>of record</u>***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Respectfully, we submit that the rejection is devoid of a proper section 103 analysis in support of the proposed modification. All that is there are conclusory statements such as the assertion that "[i]t would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Fitchett et al. with the teachings of Perrier et al. and Altemueller et al. because they each teach plant protein compositions for use in food products." (Paper No. 20081014 at 9.)

Here, what the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosures of the cited documents in the manner proposed by the Examiner to arrive at the claimed process. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). In light of this decisional authority, the rejection is incomplete. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Beyond looking at the cited documents to determine if any of them suggests doing what the inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the U.S. Patent and Trademark Office Examination Guidelines at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably

expected to have been able to do in view of that knowledge". However, no such motivation or expectation of success can be found in the cited documents.

Fitchett differs in numerous ways from the presently claimed stable powderous formulations. First, Fitchett does not teach, suggest or provide motivation for a ***powderous*** formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition. The Examiner acknowledged that Fitchett has a "deficiency in powdered formulation". (Paper 20081014 at 7.) Fitchett's disclosure of "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions" fails to suggest the claimed stable powderous formulation. (Abstract, line 2.)

Second, Fitchett provides no suggestion or motivation for the claimed powderous formulation wherein the protein in the matrix is ***cross-linked***. As noted above, there is not even a suggestion or motivation in Fitchett for a *powderous* formulation in which such protein may be cross-linked. As acknowledged by the Examiner, Fitchett "does not expressly teach cross-linking...". (Paper 20081014 at 7.) Rather, Fitchett discloses "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions." (Abstract, line 2.) No suggestion or motivation for cross-linking of protein in a matrix in a powderous formulation is provided by Fitchett.

Third, one skilled in the art would glean no suggestion or motivation ***to make a powder formulation, nonetheless to make a powder formulation as claimed in which the protein in the matrix is cross-linked*** from the disclosure of Fitchett. Fitchett lacks any disclosure of "a process for preparing a powder formulation",

as acknowledged by the Examiner. (Paper 20081014 at 7.) Fitchett thus lacks any enabling disclosure of preparing a powderous formulation, let alone a powderous formulation as claimed in which the protein in the matrix is cross-linked.

In addition, there is no suggestion or motivation in Fitchett for the claimed powderous formulation to comprise a ***fat-soluble active ingredient*** in the matrix as recited in claim 1, let alone the specific fat soluble active ingredients recited in accordance with claim 6. The Examiner acknowledged that "Fitchett "does not expressly teach ... a specific fat-soluble active ingredient...". (Id. at 7.)

Perrier's disclosure of <u>particles, such as microcapsules and nanocapsules,</u> and methods for encapsulating substances also fails to teach, suggest or provide motivation for the claimed stable ***<u>powderous</u> formulation***. Perrier discloses the use of an "acylating polyfunctional crosslinking agent" in addition to plant proteins having acylatable groups, in order to encapsulate substances. (Abstract; Col. 8, lines 35-39.) One skilled in the art would not look to a disclosure of encapsulation in attempting to achieve a powderous formulation as claimed. At bottom, there is simply no disclosure in Perrier of making a <u>powderous</u> formulation.

Furthermore, the use by Perrier of glucose in Example 9 is as the "water soluble active principle" which is encapsulated within "a wall formed of crosslinked lupin proteins" to provide "microcapsules ... which contain glucose." (Col. 10, line 66 to Col. 11, line 14.) This disclosure of the use of glucose is contrary to, and thus teaches away from, the claimed ***powderous*** formulation in which the active ingredient is a ***fat-soluble active ingredient***. Thus, Perrier fails to fill the gaps in Fitchett and, as demonstrated

below, none of the other documents relied on by the Examiner remedy the deficiencies in Perrier.

For example, Altemueller's functional food ingredient comprising an unrefined plant protein material wherein the functional food ingredient is hydrated, partially denatured and dried, fails to provide a suggestion or motivation to achieve the claimed powderous formulation. Altemueller neither discloses nor suggests a ***fat-soluble active ingredient comprised in a powderous formulation***. Nor does Altemueller disclose or suggest a fat-soluble active ingredient present in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked. Altemueller discloses that at least a portion of the unrefined (soy) protein is irreversibly denatured by high temperatures. In no way does this suggest the cross-linked matrix of the claimed powderous formulation.

Tellingly, none of Fitchett, Perrier, or Altemueller disclose or suggest a formulation of a fat-soluble active ingredient in powder form. Moreover, the dried lupin composition of Altemueller is simply not comparable to the stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Neither Rahman nor Gerrard, alone or considered together as "evidence", cure the deficiencies of the Examiner's combination. Rahman's disclosure of general aspects of drying and food preservation for any dried food composition do not provide motivation for, nor an indication as to how to make, the claimed powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Gerrard's disclosure is an overview of various forms of crosslinks found in food. Gerrard provides no disclosure that the crosslinking can be applied to lupin protein. Gerrard fails to provide motivation for, nor an indication as to how to make, the claimed powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

When considered together, Fitchett's emulsion or gel in combination with Perrier's microcapsules or nanocapsules and Altemueller's dried unrefined plant protein which may be used as a functional food ingredient, alone or in combination, do not lead one skilled in the art to the claimed stable powderous formulation. These documents have such differing and varied disclosure of formulation options such that the Examiner could only have made this combination by an improper hindsight analysis. Nor do Gerrard, which discloses a dry powder for food preservation and/or Rahman, which discloses protein crosslinking, which are cited allegedly as "evidence" by the Examiner, cure the deficiencies in the Examiner's proposed combination.

One skilled in the art would have known that numerous formulation options for a fat-soluble active ingredient would be available. Yet achieving a successful stable powderous formulation as claimed would not have been predictable to one of skill in the art. Stated another way, known options for formulation of a fat-soluble active ingredient would not have provided predictable results in achieving the claimed stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Critically, known formulation options were not "finite, identified, and predictable", as in the facts presented in *KSR Int. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). In *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ 1161, 1171 (Fed. Cir. 2008), the Court of Appeals for the Federal Circuit indicated that the Supreme Court in *KSR* "did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is 'obvious to try,' without considering the nature of the science or technology." Indeed, the Federal Circuit has recently reiterated that "merely [throwing] metaphorical darts at a board filled with combinatorial prior art possibilities" is the epitome of impermissible hindsight reconstruction. *In re Kubin*, slip op. 2008-1184, 14 (Fed. Cir. April 3, 2009). We respectfully submit that the rejection here has done no more than launch "metaphorical darts" based on the present disclosure where numerous formulation options would have been available, and for this reason as well the rejection must be withdrawn.

Moreover, as in the *Abbott* case involving producing extended release formulations, one skilled in the art would not have anticipated success in achieving the presently claimed stable powderous formulation, as "knowledge of the goal does not render its achievement obvious." *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ at 1172 (affirming the district court's determination that Abbott is likely to prevail in its claim that the patent is valid, and upholding the grant of a preliminary injunction).

In view of all of the foregoing, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Obviousness-Type Double Patenting

Claims 1, 6-9, 11 and 13 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16 and 17 of copending Application No. 10/564,635 (the '635 Application) in view of Bewert et al. (Paper No. 20081014 at 11.) It is believed that the Examiner stated "Bewert et al." in error, and that the Examiner intended to recite Perrier, which document is addressed by the Examiner within the rejection. In an effort to further prosecution, our response assumes that the Examiner intended Perrier rather than Bewert. If this is not the case, the Examiner is requested to reissue the Office Action unambiguously identifying the intended secondary document.

In making the rejection, the Examiner asserted that "the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). (Id. at 10.)

The Examiner further asserted:

> Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing sugar. The difference between the claim of copending '635 and instant claims 1 and 11 is the primary cross-linking protein. Copending '635 claim[s] 6 recites the formulation additionally comprises a plant protein and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein. ...
>
> Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635

> claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claims 6 and 7 are coextensive in scope with copending '635 claims 12 and 13....
>
> Copending '635 claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 8 is coextensive in scope with copending '635 claim 14....
>
> *Copending '197*[1/] claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to crosslinking the protein with heat treatment. The difference between instant claim 13 and copending '635 claim 17 is the primary cross-linking protein and the alternative possibility of enzymatic cross-linking instant claim 13. (emphasis added.)
>
> (Id. at 11-12.)

The Examiner acknowledged that "[t]he difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary cross-linking protein. The deficiency of using a lupin protein is cured by the teachings of Perrier et al., which teaches particles of cross-linked lupin plant proteins wherein the particles encapsulate active substances, including lipophilic active principles, as discussed above." (Id. at 12-13.)

The Examiner concluded that it would have been obvious to combine copending '635 with Perrier to produce the presently claimed invention "because both applications teach cross-linked protein food additives with a fat-soluble active ingredient

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1/ It is believed that where *"[c]opending '197"* is recited, the Examiner intended to recite "[c]opending '635". If this is not the case, the Examiner is requested to reissue the Office Action clearly and unambiguously identifying the intended "copending" application.

in the protein matrix. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a cross-linked protein food additive. [citation omitted.] Furthermore, the lupin protein of Perrier et al. would provide an added nutritive value to copending '635 and produce a more desirable product. It would be obvious to substitute the milk protein of '635 with the lupin protein of the instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e. g. vegans)." (Id. at 13.)

Perrier is summarized above.

An obviousness-type double patenting analysis is an obviousness analysis, and it must follow and be based on each of the *Graham* factors. *See Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 228 USPQ 837, 840, *cert. dismissed*, 478 U.S. 1028 (1986); and *Pac-Tec, Inc. v. Amerace Corp.*, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990); *In re Braat*, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991); *In re Braithwaite*, 154 USPQ 29, 34 n. 4 (CCPA 1967). As the Office Action reflects, although the Examiner acknowledged that the pending claims differ from the claims of each of the '952 application and the '209 patent, yet the Office Action failed to make clear ***why*** one of ordinary skill in the art "would conclude that the invention defined in the claim(s) at issue ... would have been an obvious variation of the invention defined in a claim in the patent." MPEP § 804(II)(B)(1) (8th ed. Rev. 6, Sept. 2007, pp 800-21 to 800-22).

As noted above, Perrier's disclosure of particles such as microcapsules and nanocapsules and methods for encapsulating substances fails to teach, suggest or

provide motivation for the claimed stable ***powderous formulation***. As noted previously, Perrier discloses the use of an "acylating polyfunctional crosslinking agent" in addition to plant proteins having acylatable groups, in order to encapsulate substances. (Abstract; Col. 8, lines 35-39.) One skilled in the art would not look to a disclosure of encapsulation in attempting to achieve a powderous formulation as claimed. Moreover, there is no disclosure in Perrier of making a powderous formulation. ***Perrier simply does not disclose or suggest a formulation of a fat-soluble active ingredient in powder form.***

Furthermore, the use by Perrier of glucose in Example 9 is as the "water soluble active principle" which is encapsulated within "a wall formed of crosslinked lupin proteins" to provide "microcapsules ... which contain glucose." (Col. 10, line 66 to Col. 11, line 14.) This disclosure of the use of glucose is contrary to, and thus teaches away from, the claimed ***powderous*** formulation in which the active ingredient is a ***fat-soluble active ingredient***.

As noted above in response to the obviousness rejection, one skilled in the art would have known that a large number of formulation options for a fat-soluble active ingredient would be available. With reference to the Federal Circuit's recent guidance regarding impermissible hindsight reconstruction, we respectfully submit that the rejection here has done no more than launch "metaphorical darts" based on the present disclosure where numerous formulation options would have been available, and for this reason alone the rejection must be withdrawn. *See In re Kubin*, slip op. 2008-1184 at 14.

Moreover, as in the *Abbott* case involving producing extended release formulations, one skilled in the art would not have anticipated success in achieving the presently claimed stable powderous formulation because "knowledge of the goal does not render its achievement obvious." *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ at 1172.

For the foregoing reasons, it is submitted that the obviousness-type double patenting rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

In view of all of the foregoing, entry of the amendments and withdrawal of all outstanding objections and rejections is respectfully requested. It is submitted that the application is in condition for allowance. Issuance of a Notice of Allowance is respectfully requested.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 29, 2009.

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Respectfully submitted,

By: _____

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